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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/647,488

08/25/2003

Kai-yu Tong

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750 MAIN STREET
SUITE 1400
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EXAMINER

BOCKELMAN, MARK

ART UNIT

PAPER NUMBER

3766

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/647,488	Applicant(s) TONG, KAI-YU	
	Examiner Mark W. Bockelman	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland et al., US 2003/0144710 in view of Nelson et al., USPN 5586557.

Haugland teaches a heel switch placed under the heel of a user for generating a stimulation signal when the foot is lifted during gait (Fig. 5, para. 60), an electrode adapted to contact the user's leg (Fig. 5, paras. 60-65), and a controller coupled to the heel switch and electrode for outputting a stimulation signal to the electrode (Fig. 5, paras. 78-80). Applicant's specification fails to explain the significance and differences between the four portions of the stimulation signal (i.e. rise, stimulation, extension, and fall portions) other than merely being depicted in Fig. 4. To the extent that it is understood what the different portions are, Haugland is interpreted as disclosing a stimulation signal having a rise portion, a stimulation portion, an extension portion and a fall portion (paras. 90-91). Nelson also teaches a device for evaluating the gait of an individual using a heel switch and calculating a duration of use and a number of steps taken over that duration (column 3, lines 15-17) to determine an ambulation index. Since Nelson is directed to a device for analyzing and monitoring ambulation during

rehabilitation (column 1, lines 11-15), it would have been obvious to incorporate recording the number of steps taken during gait as taught in Nelson into the device of Haugland to more effectively monitor a patient's recovery status during rehabilitation.

Claims 2 and 4-6, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland in view of Nelson as applied to claim 1 above, and further in view of Smith et al., USPN 5485402.

As discussed above, Haugland teaches a heel switch placed under the heel of a user for generating a stimulation signal when the foot is lifted during gait (Fig. 5, para. 60), an electrode adapted to contact the user's leg (Fig. 5, paras. 60-65), and a controller coupled to the heel switch and electrode for outputting a stimulation signal to the electrode (Fig. 5, paras. 78-80). The controller is contained in a housing which also includes a receiver for receiving wireless signals from a remote unit (paras. 80, 85), and stores stimulation data (para. 80). The remote unit may be a hand-held computer that is removably coupled to the controller (para. 85). Again, Haugland is interpreted as disclosing a stimulation signal having a rise portion, a stimulation portion, an extension portion and a fall portion (paras. 90-91). Similarly, Applicant's specification fails to discuss the stimulation data as including a stimulation level, a rise time, a stimulation time, a stimulation time, an extension time, a fall time, a pulse form, a triggering period, a triggering method and a triggering criteria. To the extent that these features are understood, they are considered to be inherently present in Haugland (paras. 73, 79-80, 85-92, 95, 114, 129-133).

While Nelson teaches measuring a duration of use and number of steps taken during that duration, Nelson does not teach recording the number of steps taken in a predetermined duration such as an hour, a day, or a period of dates. Smith on the other hand, discloses storing a number of steps taken during a selected time interval, including hourly or daily (column 4, line 52 - column 5, line 25, Figs. 4-5). Like Nelson, Smith is also directed to a gait activity monitor which may be used for patient rehabilitation. Therefore, it would have been obvious to one of ordinary skill in the art to specify a time interval and count and store the number of steps taken during that interval as taught by Smith, while rehabilitating a patient using the device taught by Haugland modified by Nelson, to provide a more effective means of monitoring a patient's progress during rehabilitation.

Claims 7-8 rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland in view of Nelson and Smith as applied to claims 2, 4-6 and 9 above, and further in view of Sieracki et al, US 2004/0143302.

Haugland, Nelson and Smith disclose each feature of the claimed invention, as discussed above, except for the limitation that the computer may be a Personal Digital Assistant and uses Windows as the graphic user interface. Both of these features are well known. For example, there are several well known types of computers, including desktops, laptops, and PDAs. Moreover, many of these types of computers and other electronic devices (eg cell phones) also use Windows. Sieracki is one example of a programmable therapeutic stimulating device which uses a PDA as the external

controller (Fig. 1). It would have been obvious to one of ordinary skill in the art to use a PDA as the computer and/or to use Windows in the computer of Haugland as these are standard options for any application requiring a computer.

Response to Arguments

Applicant's arguments filed 5-15-2007 have been fully considered but they are not persuasive. Applicant argues that a narrower interpretation of the phrase "programmed to record a duration of use and a number of movements during the duration of use", should be applied with respect to claim 1 and the rejection withdrawn. The examiner disagrees for two reasons. First the combination of Haugland et al and Nelson et al has each and every element in the claims as explained above using the normal interpretations of the words. Secondly, applicant casts a narrower interpretation of the Nelson et al reference teaches. The reference teaches that the device is set up so as to be able to record a duration and the number of steps taken to establish an ambulation index. While an example is stated that the patient is asked to walk a short distance of 3 to 6 meters, this in no way means that the device can only count and record for a short distance (period of time), it merely means that Nelson et al considers that to be a sufficient operation parameter so as to establish an index for that period of time. The examiner considers the teaching to provide motivation for providing a recordation device in the Haugland et al. device and that one may operate it in and fashion suitable to establish the index. The device can be over and over again to record such criteria to establish improvement. In this respect the further addition of Smith et al

does not teach away from the Nelson et al reference et al. It is cited to show that establishing gait indices and report generation may take longer periods of time, or selected periods of time, of gait activity recordation. Thus, applicant's arguments are deemed unpersuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272 -4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark W Bockelman/
Primary Examiner, Art Unit 3766

April 27, 2008